

Notice of Allowability	Application No.	Applicant(s)	
	10/522,037	NALIN ET AL.	
	Examiner	Art Unit	
	SUE LIU	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/31/10.
2. ☒ The allowed claim(s) is/are 48-52, 54-65 and 67-70.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>10/28/10</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/SUE LIU/
Primary Examiner, Art Unit 1639

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Frank C. Eisenschenk on 10/28/10.

The application has been amended as follows:

The instant **Abstract** is rewritten as the followings:

“The present invention relates to methods for the identification or cloning of polynucleotides encoding a selected phenotype, particularly from environmental DNA. In a specific embodiment, the method comprises (i) cloning environmental DNA fragments into *E. coli* cloning vectors to produce a metagenomic library, (ii) identifying or selecting cloning vectors in the library which contain DNA fragments having a particular characteristic of interest, (iii) modifying the identified or selected cloning vectors into shuttle or expression vectors for transfer and integration in a selected host cell, (iv) transferring the modified cloning vectors into the selected host-cell and (v) identifying or cloning the DNA fragments contained in the modified cloning vectors which encode the selected phenotype in the selected host cell.”

Art Unit: 1639

Claim 48 is rewritten as follows:

“A method for the identification or cloning of polynucleotides encoding a selected phenotype, the method comprising (i) cloning environmental DNA fragments into *E. coli* cloning vectors and propagating said vectors in *E. coli* to produce a metagenomic library in *E. coli* cells, (ii) identifying or selecting cloning vectors in said library which contain DNA fragments having a particular characteristic of interest, (iii) inserting a target polynucleotide construct into said identified or selected cloning vectors in a region of said identified or selected cloning vectors distinct from the DNA fragments having a particular characteristic of interest to form modified cloning vectors, wherein said target polynucleotide construct comprises a nucleic acid encoding an origin of transfer functional in *E. coli* and a nucleic acid encoding an integrase functional in a selected recipient host cell having a genome distinct from *E. coli*, thereby conferring to the modified cloning vectors the ability to be transferred into said selected recipient host cell, (iv) transferring the modified cloning vectors into said selected recipient host cell and integrating said modified cloning vectors and/or the DNA fragments having a particular characteristic of interest which they contain into the genome of said selected recipient host cell and (v) identifying or cloning the DNA fragments contained in said modified cloning vectors which encode said selected phenotype in said selected recipient host cell,

wherein said selected recipient host cell is a microorganism or host cell other than *E. coli*.”

Claim 67 is rewritten as follows:

Art Unit: 1639

“A method for the identification or cloning of polynucleotides encoding a selected phenotype, the method comprising:

(i) cloning environmental DNA fragments into *E. coli* cloning vectors and propagating said cloned environmental DNA fragments in *E. coli* to produce a metagenomic library;

(ii) identifying or selecting cloning vectors in said library which contain DNA fragments having a particular characteristic of interest or encoding a selected phenotype;

(iii) inserting a target polynucleotide construct into said identified or selected cloning vectors in a region of said identified or selected cloning vectors distinct from the DNA fragments having a particular characteristic of interest to form modified cloning vectors, wherein said target polynucleotide construct comprises a nucleic acid encoding an origin of transfer functional in *E. coli* and a nucleic acid encoding an integrase functional in a selected recipient host cell having a genome distinct from *E. coli*, thereby conferring to the modified cloning vectors the ability to be transferred into said selected recipient host cell;

(iv) transferring the modified cloning vectors into said selected recipient host cell and integrating said modified cloning vectors and/or the DNA fragments having a particular characteristic of interest which they contain into the genome of said selected recipient host cell; and

(v) identifying or cloning the DNA fragments contained in said modified cloning vectors which encode said particular characteristic of interest in said selected recipient host

Art Unit: 1639

cell, wherein said selected recipient host cell is a microorganism or host cell other than *E. coli*.”

Claim Status

Claims 1-47, 53 and 66 have been cancelled.

Claims 48-52, 54-65 and 67-70 are allowed as amended above.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/
Primary Examiner, AU 1639
10/28/10